ATTN: James Mullaner
Nuclear Regulatory
Region III

Dear Jim:

Enclosed is (I hope!) the checklist needed. I asked the help of Ms Sandra Nusen of NC Systems, Boulder CO, who is selling us the EQUIPMENT. If PROBLEMS blame her! (Just Kidding!)

Please let me know if there is anything else needed. Note that I refer to several of the ATTACHMENTS which should have been in the ORIGINAL Request we sent to you. Many Thanks!

Tom Ryan (TomRyan)

P.S. I'll call in PM of 28 May to confirm your Receipt of this and try to answer any Questions!

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use
(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

☐ Yes ☒ No.	This response includes security-related sensitive information (see Section 5.2) which is included in Attachment all and marked "Security-related information – withhold under 10 CFR 2.390"

**See Attachment A

INCLUDED

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
	Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
	F-18	Any	____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	O-15	Any	____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	C-11	Any	____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	Any byproduct material permitted by 10 CFR 35.300	Any	____ millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	___millicuries	Administration of I-131 sodium iodide.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ______)	Sealed source or device (Manufacturer ______) Model No.______)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ______)	Sealed source or device (Manufacturer ______) Model No.______)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ______)	Sealed source or device (Manufacturer ______) Model No.______)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ______)	Sealed source or device (Manufacturer ______) Model No.______)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.

Attachment I-a

Radiation Monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

We have developed and will implement and maintain written survey meter calibration procedures (10 CFR 20.1501 and 10 CFR 35.61)

See Attachement I for equipment description.

We reserve the right to upgrade our survey instruments as needed and as long as they are in compliance.

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or mfr. instructions.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use
(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
				radiosurgery device.
	Any byproduct material under 10 CFR 31.11	Prepackaged kits	___millicuries	*In vitro* studies.
	Depleted uranium	Metal	___kilograms	Shielding in a teletherapy unit.
	Depleted uranium	Metal	___kilograms	Shielding in a linear accelerator.
	Any radionuclide in excess of 30 millicuries for use in calibration, transmission, and reference sources. (List radionuclide: _____)	Sealed source or device (Manufacturer _____, Model No. _____) See Attachment I	___millicuries	For use in a Manufacturer _____, Model No. _____ for calibration and checking of licenses's survey instruments.
	Americium-241	Sealed source or device (Manufacturer _____, Model No. _____)	___millicuries per source and ___millicuries total	Use as an anatomical marker.
	Plutonium (principal radionuclide Pu-238)	*Sealed sources*	___millicuries per source and ___grams total	As a component of. Manufacturer _____, Model No. _____ *nuclear-powered* cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explantation, recovery, disposal, and implantation.
	Other	*Form or* Manufacturer/Model No. _____	___*millicuries*	*Purpose of use* _____

** See Attachment I
INCL-009

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Radiation Safety Officer Name: Dr. Apuri	*For an individual previously identified as an RSO on an NRC or Agreement State license or permit:*	
	Previous license number (if issued by the NRC), or a copy of a license (if issued by an Agreement State), or a copy of a permit (if issued by an NRC master materials licensee) on which the individual was specifically named as the RSO.	☐
	For an individual qualifying under 10 CFR 35.57(a)(3):	
	Documentation that the individual was: • the RSO for only the medical uses of accelerator-produced radioactive material or discrete sources of Ra-226 included in the definition of byproduct material as a result of the EPAct; • the RSO for the medical uses of these materials before or during the effective period of NRC's waiver of August 31, 2005.	☐
	For an individual qualifying under 10 CFR 35.50(a):	
	Copy of certification by a specialty board whose certification process has been recognized[10] by NRC or an Agreement State under 10 CFR 35.50(a).	☐
	AND	
	Description of the training and experience specified in 10 CFR 35.50(a) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.	☐
	AND	
	Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed training in and experience required for certification, as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐

**See Attachment B in original package already sent

[10]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

APPENDIX C

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application	
Item 7: Authorized Users for medical uses: Name(s), (including license number authorizing practice of medicine, podiatry, or dentistry if not provided previously or in attachment); Requested uses for each individual	*For an individual previously identified as an AU on an NRC or Agreement State license or permit:* Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested.	☐	
Dr. Tom Ryan	*For an AU requesting authorization for an additional medical use:* Description of the additional training and experience to demonstrate the AU is also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 10 CFR 35.290 (b), 35.396, 35.390(b)(1)(ii)(G), or 35.690(c)). **AND**	X	See Attached
	A preceptor attestation, if required (e.g., attestation is required to meet the requirements in 10 CFR 35.396, 35.390(b)(1)(ii)(G), or 35.690(c)).		
	For an individual qualifying under 10 CFR 35.57(b)(3): Documentation that the physician, podiatrist, or dentist: • used only accelerator-produced radioactive materials, or discrete sources of Ra-226, or both, for medical uses before or during the effective period of NRC's waiver of August 31, 2005; and • used these materials for the same medical uses requested.	☐	
	For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board-certified: Copy of the certification(s) by a specialty board(s) whose certification process has been recognized[12] by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested. **AND**	☐	

[12] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.	☐
	AND	
	Written attestation, signed by a preceptor AMP, that the required training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved.	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
Item 7: Authorized User for nonmedical uses	*Note:* For purposes of this section of the table, the term "authorized user" is used to mean individuals authorized for the nonmedical uses described. See Sections 8.11 and 8.12.	
	For an individual previously authorized for nonmedical use on an NRC or Agreement State license or permit:	
Name(s): Requested types, quantities, and nonmedical uses for each individual	Previous license number (*if* issued by the NRC), or a copy of the license (*if* issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AU for the types, quantities, and uses requested.	☐
	For individuals qualifying under 10 CFR 30.33(a)(3):	
	Documentation of the individual's training and experience demonstrating that the individual is qualified to use the types and quantities of licensed materials for the requested uses.	☐
Item 9: Facility Diagram	A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:	☒
	• Guidance in Section 9.2 was reviewed and security-related sensitive information provided is marked accordingly.	☒
	• Drawings should be to scale, indicating the scale used.	☐

** See Attached

APPENDIX C

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	• Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, location of direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility or production area of PET radioactive drugs under 10 CFR 30.32(j), and areas where higher energy gamma- emitting radionuclides (e.g., PET radionuclides) are used;	☒
	• Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms, indicating whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and	☒
	• Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe).	☐
	In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.	☐
Item 9: Radiation Monitoring Instruments	A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."	☒
	AND/OR	
	A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61."	☐
	AND	
	A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.	☐
	AND	
	A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."	☐
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	☐

** See Attachment F IN original package

** See Attachment original package

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	When administering dosages of alpha-emitting unsealed byproduct material in other than unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72 or 10 CFR 30.32(j), • A statement that: "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation." **OR**	☐
	• We are providing a description of the dosage measurement equipment, the nationally recognized calibration standard (or manufacturer's calibration instructions), and dosage measurement procedures.	X
Item 9: Therapy Unit - Calibration and Use	We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.	☐
Item 9: Other Equipment and Facilities	Guidance in Section 5.2 was reviewed and security-related information provided is marked accordingly.	☐
	Attached is a description, identified as Attachment 9.4, of additional facilities and equipment.	☐
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	☐
	For PET radionuclide use, PET radioactive drug production, and radiopharmaceutical therapy programs, we are providing a description of the additional facilities and equipment for these uses.	☐
	For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following: • Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room; • Area radiation monitoring equipment; • Viewing and intercom systems (except for LDR units); • Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room; • Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and • Emergency response equipment.	☐ ☐ ☐ ☐ ☐ ☐

APPENDIX C

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Safety Procedures and Instructions	Attached are procedures required by 10 CFR 35.610.	☒ See Attachments
	Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	☐
Item 10: Occupational Dose	A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.' " **OR**	X See Attachments
	A description of an alternative method for demonstrating compliance with the referenced regulations.	☐
Item 10: Area Surveys	A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."	X
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."	X
Item 10: Spill/Contamination Procedures	A statement that: "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."	X
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested: ____________________ **AND**	X
	Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested. **AND**	☐
	Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	☐
Item 10: Minimization of Contamination	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.15, 8.16, 8.21, 8.25, 8.27, and 8.29, on the topics: facilities and equipment, facility diagram, Radiation Protection Program, safety program, and waste management.	N/A

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 11: Waste Management	A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."	X
	Attached is a description of the radioactive waste incinerator facility and related portions of the Radiation Safety Program (10 CFR 20.2004).	☐
	Attached is a request to receive potentially contaminated radiation transport shields from consortium members receiving PET radioactive drugs noncommercially transferred under 10 CFR 30.32(j) authorization.	☐